



DEPARTMENT OF HEALTH AND HUMAN SERVICES

U. S. Food and Drug Administration
San Francisco District

1430 Harbor Bay Parkway
Alameda, CA 94502
Tel: (510) 337-6700
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November 21, 2013

Joseph G. Sharpe, Executive Vice President
Conceptus Inc.
1101 McCarthy Blvd.
Milpitas, CA 95035

Reference: FEI 3004268587

Dear Mr. Shoberg,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at 331 E Evelyn Ave., Mountain View, CA 94041 on May 30 to June 26, 2013 by the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 C.F.R. 20.64 (d) (3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continuously works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

If there is any question about the released information, feel free to Cindy Ford, Supervisory Consumer Safety Officer at (408) 291-7548 x1108 or write to:

Mark Chan, Supervisory Consumer Safety Officer
Food and Drug Administration San Jose Resident Post
96 North Third Street, Suite 420
San Jose, CA 95112

Darlene Almogela, Director of Investigations
For Kathleen M. Lewis, J.D., District Director, San Francisco District

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